Otto Bock®
QUALITY FOR LIFE

K111045

JUL 15 2011

510(k) SUMMARY of SAFETY and EFFECTIVENESS

A. General Information

1. Submitter's Name.:	OTTO BOCK Health Care, LP
2. Address:	Two Carlson Parkway North, Suite 100 Minneapolis, Minnesota USA 55447-4467
3. Telephone:	763-253-5610
4. Contact Person:	William Kabitz, Quality Assurance Manager
5. Date Prepared:	March 29th, 2011
6. Registration Number:	2182293

B. Device

1. Name:	Centro Family of Wheelchairs
2. Trade Name:	Centro S1 and Centro A3
3 .Common Name:	Manual Wheelchair
4. Classification Name:	Wheelchair, Manual
5. Product Code:	IOR
6. Class:	I
7. Regulation Number:	890.3850

C. Identification of Legally Marketed Predicate Device

1. Name:	Start – Mobile Positioning System
2. Manufacture:	Otto Bock HealthCare, Mobility Solutions
3. K Number:	K052681
4. Date Cleared:	October 06, 2005

D. Description of the Device

The Centro Wheelchairs are an uncomplicated line of wheelchair (S1 and A3 models) and are appropriate for short-term use. The Centro wheelchairs are very robust, which ensures that they will have a long service life. The product has a functional knee lever lock. The stable cross brace ensures that it folds easily. Thus, the Centro can be folded to a very small size easily, and it is convenient to transport or space-saving for storage.

The Centro with 12" rear wheels offers the possibility to use it as a functional transit wheelchair. Due to the nylon covering of seat and back upholstery, the chairs are easy to clean or disinfect and thus always quickly ready for use.

Features

- Silver-colored frame made of aluminum or steel
- Footrests with swing in/swing out function, removable
- Side panels adjustable, can be swung away to the rear
- Small folded size
- Single stable steel cross-brace
- 8 Variants available from stock
- 6" caster of solid rubber
- Variant with drum brakes available
- Tip-Assist included
- Knee lever lock standard

Options

- Anti-tipper
- Desk Side Panels
- Fold-down Footrests
- Lap belt
- Transfer Version with 12" Drive Wheel
- Heel Band
- Seat Cushion Sizes
- Crutch holder

E. Indicated Use Statement

The Centro wheelchairs are designed solely for individual use by persons who are unable to walk or who have a walking impediment, and can be operated either by the patient or by another person.

F. Field of Application

The Centro S1 and A3 standard wheelchairs are suitable for patients with walking impediments/inability due to, but not limited to:

- Palsies/Paralyses
- Defective and/or deformed limbs
- Loss of limb (leg amputation)
- Joint contractures/defects
- Diseases such as cardiac or circulatory insufficiency, balance disorders or cachexia, as well as geriatric patients who still have usable residual strength in the upper limbs.

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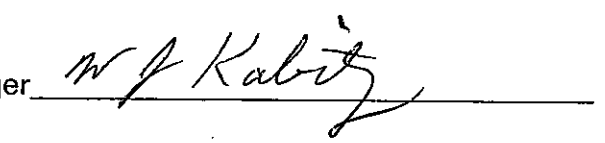
G. Technological Characteristics Summary

TÜV – test for medical devices (requirements according to the European Directive for Medical Products 93/42/EEC, DIN EN 12183:1999, DIN EN 12182:1999, and tests specified for wheelchairs (DIN EN 1888). The product is certified for CE conformity and its suitability for daily use was verified in a field test.

Additional product testing to the following ISO standards was conducted by Berlin Cert, Institute for Testing and Certification of Medical Devices: (http://www.berlincert.de/de/frameset.php?lang=en&page=home)

- DIN EN 12182:1999 – Technical aids for disabled persons
- DIN EN 12183:1999 – manually propelled wheelchairs – requirements & test methods
- ISO 7176-1:1999 – Wheelchairs – Part 3: Determination of static stability
- ISO 7176-3:2003 – Wheelchairs – Part 3: Determination of efficiency of brake
- ISO 7176-5:1986 – Wheelchairs – Part 5: Determination of dimensions, turning space
- ISO 7176-7:1998 – Wheelchairs – part 7: Measurement of seating & wheel dimensions
- ISO 7176-8:1998 – Wheelchairs – Part 8: Requirements, static impact/fatigue strengths
- ISO 7176-15:1996 – Wheelchairs – Part 15: Requirement for labeling

Signatures:

Quality Assurance Manager 

President & CEO US Healthcare 

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OTTO Bock Health, Care, LP
% Mr. William Kabitz
Quality Assurance Manager
Two Carlson Parkway North, Suite 100
Minneapolis, Minnesota 55447

JUL 15 2011

Re: K111045
Trade/Device Name: Centro Manual Wheelchair
Regulation Number: 21 CFR 890.3850
Regulation Name: Mechanical wheelchair
Regulatory Class: Class I
Product Code: IOR
Dated: April 1, 2011
Received: April 18, 2011

Dear Mr. Kabitz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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APPENDIX F

Indications For Use Form

510(k) Number (if known): To be determined

Device Name: Centro Manual Wheelchair

Indications for Use:

The Centro wheelchairs are designed solely for individual use by persons who are unable to walk or who have a walking impediment, and can be operated either by the patient or by another person. Centro wheelchairs are suitable for patients with walking impediments/inability due to, but not limited to:

- Palsies/Paralyses
- Defective and/or deformed limbs
- Loss of limb (leg amputation)
- Joint contractures/defects
- Diseases such as cardiac or circulatory insufficiency, balance disorders or cachexia, as well as geriatric patients who still have usable residual strength in the upper limbs.

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K111045

Prescription Use ____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE
CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)